1.0 *Purpose:* The purpose of this policy is to inform all investigators and research personnel who engage in human subjects research at the University of South Florida (USF) or research under the purview of the USF Institutional Review Board (IRB) of the mandatory training requirements for the protection of human subjects.

2.0 *Policy:* It is the policy of the USF IRB that all individuals who engage in human subjects research participate in a USF IRB approved, comprehensive training program prior to receiving full approval by the USF IRB for new and continuing research. This policy extends to anyone involved in the conduct of the research including individuals who collect data about human subjects, those conducting study procedures or interventions, and those who have access to private, identifiable information. This policy applies to all human subjects research regardless of funding or source of sponsorship. The requirement for human research protection education is valid for two years.

3.0 *IRB Approved Education Programs:*  
3.1 **Foundation Course:** Investigators and research personnel must participate in a foundations course for the protection of human subjects prior to any involvement in human subjects research. Individuals are encouraged to participate in the USF Foundations Course, the Collaborative Institution Training Initiative (CITI) program, or the National Cancer Institute/National Institutes for Health program for human subjects research. Investigators must take either the Biomedical and/or Social Behavioral modules as appropriate for the type of research being conducted.

3.2 **Continuing Education:** Recertification must take place two years from the date of initial certification in human research protection education. Recertification can take place with either the USF Foundations Course, the CITI Refresher Course or another USF IRB approved program.

3.3 The Veterans Affairs and other Affiliates may have specific requirements for human research protection education which are in addition to the USF HRPP requirements.

3.4 Additional human research protection education may be required by certain funding agencies (e.g., Department of Defense or the Department of Justice).

3.5 The USF IRB will accept education provided by the Family Health International program entitled “Research Ethics Training Curriculum for Community Representatives” for lay research personnel who speak Spanish and are not fluent in English.
3.6 All USF IRB approved programs are listed on the IRB website.

3.7 Investigators transferring from other institutions can submit their CITI certificate as documentation of human subjects protection education; however, institutional based programs will not be considered approved education programs due to the inability of the USF IRB to review and evaluate these programs.

3.8 Researchers who perform research which is exempt from IRB review and oversight and that which is considered Not Human Subjects Research (NHSR) must complete one of the two foundations courses outlined above. Recertification is not required for research deemed exempt or not human subjects research if the research is completed within the two year certification period. However, if research will continue beyond the two year certification period, education must be renewed.

3.9 Responsible Conduct of Research (RCR) is a separate research training requirement from the human subjects protection education certification and will not substitute for the requirements outlined in this policy.

4.0 Failure to Comply:

4.1 Investigators and all research personnel included on the USF IRB application must comply with this policy and maintain current certification for new applications to receive approval by the USF IRB.

4.2 The USF IRB has the authority to suspend or withhold approval on projects that involve investigators and research personnel who fail to meet the education requirements as outlined in this policy.